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# Atara Biotherapeutics Announces Submission of Investigational New Drug Application for ATA3219 for Treatment of Lupus Nephritis

*ATA3219 is an Allogeneic CAR T-Cell Therapy Targeting CD19+ B Cells to Potentially Address the Root Cause of Lupus Nephritis (LN)*

*ATA3219 Is Designed to Combine the Natural Biology of Unedited T Cells and the Benefits of an Allogeneic CAR T Approach With Preclinical Data Demonstrating Potential Efficacy in LN*

*Second IND Submission for ATA3219, Following Non-Hodgkin's Lymphoma (NHL) IND Clearance Received in Q3 2023*

THOUSAND OAKS, Calif.--(BUSINESS WIRE)-- Atara Biotherapeutics, Inc. (Nasdaq: ATRA), a leader in T-cell immunotherapy, leveraging its novel allogeneic Epstein-Barr virus (EBV) T-cell platform to develop transformative therapies for patients with cancer and autoimmune diseases, today announced its recent submission of an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for the use of ATA3219 as a monotherapy for the treatment of systemic lupus erythematosus (SLE) with kidney involvement (lupus nephritis [LN]).

"Despite therapeutic advances, there remains high unmet need in lupus nephritis, where standard of care and approved therapies have limited efficacy that often rely on multi-year, if not lifelong immune suppression," said Rajani Dinavahi, Chief Medical Officer at Atara. "We are dedicated to advancing medical breakthroughs with innovative cell therapies that truly make a difference. We look forward to working with the FDA to initiate this study and advance ATA3219 into the clinic to potentially bring a new disease-modifying option for patients suffering from this chronic disease."

ATA3219 is an allogeneic anti-CD19 chimeric antigen receptor (CAR) T-cell therapy. ATA3219 consists of allogeneic EBV T cells that express a CAR targeting CD19 antigen, which is present on the cell surface of most B cells involved in B-cell mediated autoimmune diseases. Key features of ATA3219 include clinically validated technologies designed for T-cell memory phenotype and associated durability, optimized expansion and mitigated exhaustion from a novel 1XX costimulatory domain, and retained endogenous T-cell receptor as a key survival signal that contributes to cell persistence. Using an allogeneic approach may address the significant technical, operational, manufacturing cost, and access challenges seen with autologous CAR T products, permitting the rapid treatment of potentially thousands of high-risk patients. Treatment will be facilitated for patients and physicians in avoiding apheresis and lengthy patient-by-patient manufacturing as ATA3219 would be rapidly available as an off-the-shelf treatment from finished product inventory.

“We are particularly excited to bring this allogeneic CD19 CAR T to the clinic as it has been designed to offer a differentiated profile by incorporating multiple clinically validated attributes,” said Cokey Nguyen, Chief Scientific and Technical Officer at Atara. “Our goal is to demonstrate that ATA3219 can provide deep and durable remission, allowing the immune system to reset and potentially transform a new therapeutic area with an off-the-shelf CAR T approach.”

Proof of concept for a CD19 CAR T approach in autoimmune disease was first demonstrated in early academic results from an investigator-sponsored study showing 100% (8/8) of LN patients rapidly attaining drug-free, durable remission with an autologous CD19-targeted CAR T therapy. The therapy eliminated the pathogenic, autoreactive B cells and allowed healthy B cells to return after treatment, enabling the patients’ immune system to function normally again with associated improvement of clinical symptoms.[1] These early proof of concept clinical data with CD19 targeted CAR T support further development of CAR T for LN with differentiated and off-the-shelf allogeneic approaches.

The ATA3219 IND submission includes robust *in vitro* data reflecting the CD19 antigen-specific functional activity of ATA3219 and CAR-mediated activity against B cells from SLE patients. ATA3219 led to near-complete CD19-specific B-cell depletion compared to controls.

LN is a serious and most common complication of SLE, a chronic multisystem autoimmune disease. The prevalence of SLE in the U.S. is 73 per 100,000 people, afflicting more than 200,000 U.S. patients alone, and occurs in women much more commonly than men. Up to 60% of adult patients with SLE develop renal disease during the course of their illness, and up to 70% of patients with LN are refractory to standard immunosuppressive therapies. Despite recent advances in treatment strategies, the response rate using existing therapies remains low, with significant risk of long-term morbidity and mortality associated with refractory LN.

**About ATA3219**

ATA3219 combines the natural biology of unedited T cells with the benefits of an allogeneic therapy. It consists of allogeneic Epstein-Barr virus (EBV)-sensitized T cells that express a second generation CD19 CAR construct for the treatment of CD19+ relapsed or refractory B-cell malignancies, including B-cell non-Hodgkin’s lymphoma and B-cell mediated autoimmune diseases including systemic lupus erythematosus (SLE) with kidney involvement (lupus nephritis [LN]). ATA3219 has been optimized to offer a potential best-in-class profile, featuring off-the-shelf availability. It incorporates multiple clinically validated technologies like the modified CD3ζ signaling domain (1XX) that optimizes expansion and mitigates exhaustion, enrichment for a less differentiated memory phenotype for robust expansion and persistence and retains the endogenous T-cell receptor without gene editing as a key survival signal for T cells contributing to persistence.

**Next-Generation Allogeneic CAR-T Approach**

Atara is focused on applying Epstein-Barr virus (EBV) T-cell biology, featuring experience in over 600 patients treated with allogeneic EBV T cells, and novel chimeric antigen receptor (CAR) technologies to meet the current limitations of autologous and allogeneic CAR therapies head-on by advancing a potential best-in-class CAR T pipeline in oncology and

autoimmune disease. Unlike gene-edited approaches aimed at inactivating T-cell receptor (TCR) function to reduce the risk for graft-vs-host disease, EBV T cells maintain expression of native TCRs that promote in vivo functional persistence while also demonstrating inherently low alloreactivity due to their recognition of defined viral antigens and partial human leukocyte antigen (HLA) matching. A molecular toolkit of clinically-validated technologies—including the 1XX costimulatory domain designed for better cell fitness and less exhaustion while maintaining stemness—offers a differentiated approach to addressing significant unmet need with the next generation CAR T.

**About Atara Biotherapeutics, Inc.**

Atara is harnessing the natural power of the immune system to develop off-the-shelf cell therapies for difficult-to-treat cancers and autoimmune conditions that can be rapidly delivered to patients within days. With cutting-edge science and differentiated approach, Atara is the first company in the world to receive regulatory approval of an allogeneic T-cell immunotherapy. Our advanced and versatile Epstein-Barr virus (EBV) T-cell platform does not require T-cell receptor or HLA gene editing and forms the basis of a diverse portfolio of investigational therapies that target EBV, the root cause of certain diseases, in addition to next-generation AlloCAR-Ts designed for best-in-class opportunities across a broad range of hematological malignancies and B-cell driven autoimmune diseases. Atara is headquartered in Southern California. For more information, visit atarabio.com and follow @Atarabio on X and LinkedIn.

**Forward-Looking Statements**

This press release contains or may imply "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. For example, forward-looking statements include statements regarding the development, data, timing and progress, as applicable, of: (1) the ATA3219 program, including the progress of the IND for lupus nephritis; (2) the potential characteristics and benefits of ATA3219, including the potential safety, efficacy, tolerability and persistence of ATA3219, as well as the CD19 antigen-specific functional activity of ATA3219 and CAR-mediated activity against B cells from SLE patients; (3) the manufacture of ATA3219, including scalability; and (4) the Company's planned clinical study of ATA3219 to treat lupus nephritis, including the timing thereof. Because such statements deal with future events and are based on Atara's current expectations, they are subject to various risks and uncertainties and actual results, performance or achievements of Atara could differ materially from those described in or implied by the statements in this press release. These forward-looking statements are subject to risks and uncertainties, including, without limitation, risks and uncertainties associated with the costly and time-consuming pharmaceutical product development process and the uncertainty of clinical success; the ongoing COVID-19 pandemic and the wars in Ukraine and the Middle East, which may significantly impact (i) our business, research, clinical development plans and operations, including our operations in Southern California and Denver and at our clinical trial sites, as well as the business or operations of our third-party manufacturer, contract research organizations or other third parties with whom we conduct business, (ii) our ability to access capital, and (iii) the value of our common stock; the sufficiency of Atara's cash resources and need for additional capital; and other risks and uncertainties affecting Atara's and its development programs, including those discussed in Atara's filings with the Securities and Exchange Commission , including

in the “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” sections of the Company’s most recently filed periodic reports on Form 10-K and Form 10-Q and subsequent filings and in the documents incorporated by reference therein. Except as otherwise required by law, Atara disclaims any intention or obligation to update or revise any forward-looking statements, which speak only as of the date hereof, whether as a result of new information, future events or circumstances or otherwise.

[1]Mueller, F., et al. CD19-Targeted CAR-T Cells in Refractory Systemic Autoimmune Diseases: A Monocentric Experience from the First Fifteen Patients. Blood 2023; 142 (Supplement 1): 220.

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**Investor and Media Relations:**
Jason Awe, Ph.D.
Senior Director, Corporate Communications & Investor Relations
(805) 217-2287
jawe@atarabio.com

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